Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

KML-Experten berichten

63rd ASH Meeting 2021

Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

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Multiples Myelom (MM)

Offenlegung potentieller Interessenskonflikte

LymphomKompetenz KOMPAKT – ASH2021 wird in Kooperation mit sechs unterstützenden Firmen durchgeführt.
Meine persönlichen Disclosures betreffen:

Anstellungsverhältnis, Führungsposition	
Beratungs-/ Gutachtertätigkeit	Amgen, Adaptive Biotech, Bristol-Myers Squibb, Celgene, GSK, Janssen, Karyopharm, Oncopeptides, Sanofi, Takeda
Besitz von Geschäftsanteilen, Aktien oder Fonds	
Patent, Urheberrecht, Verkaufslizenz	
Honorare	Amgen, Adaptive Biotech, Bristol-Myers Squibb, Celgene, GSK, Janssen, Karyopharm, Roche, Sanofi, Takeda
Finanzierung wissenschaftlicher Untersuchungen	Amgen, Celgene, Sanofi, Janssen (Institution)
Andere finanzielle Beziehungen	
Immaterielle Interessenkonflikte	

Kapitel 1

Erstlinientherapie von Patienten, die sich für eine autologe Transplantation eignen: Wie wichtig ist die primäre Quadruplet-Therapie

Daratumumab (DARA) Plus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Patients (Pts) with Transplant-Eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Analysis of Griffin after 24 Months of Maintenance

79

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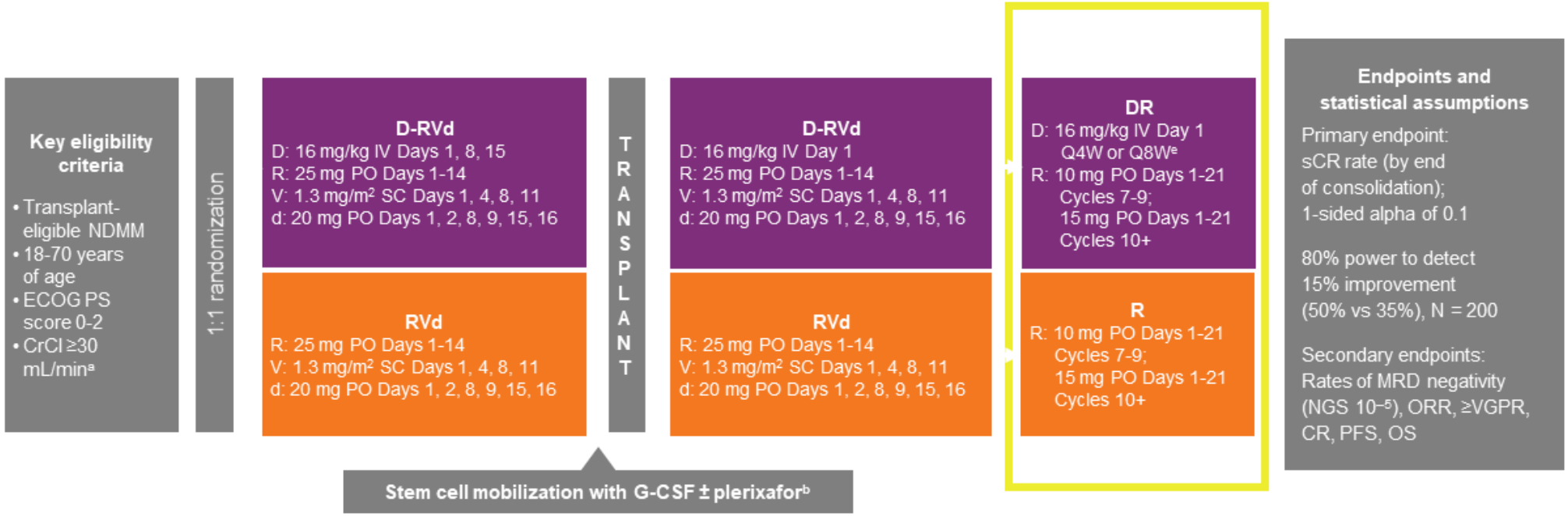
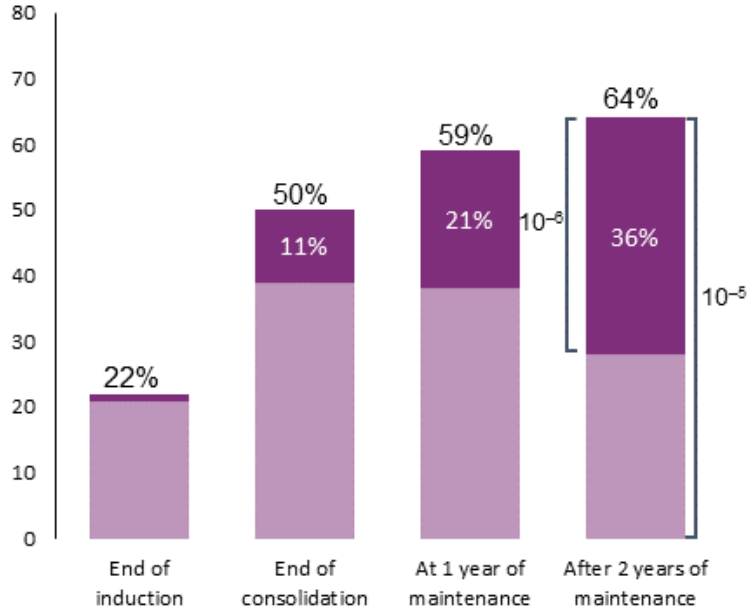
GRIFFIN: Study Design of the Randomized Phase

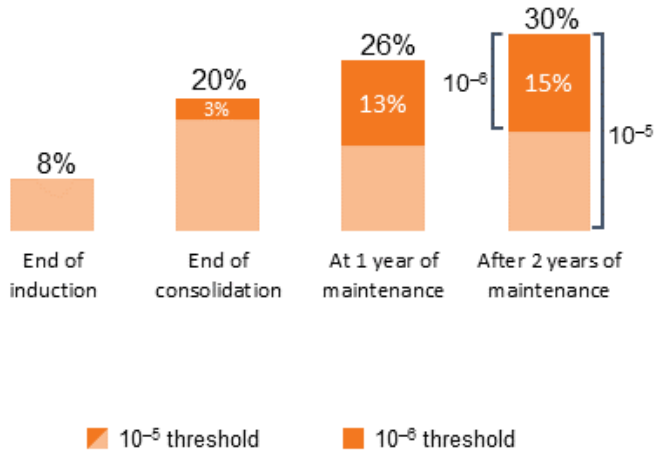
- **Phase 2 study of D-RVd versus RVd in transplant-eligible NDMM, 35 sites in the United States with enrollment between December 2016 and April 2018**



ECOG PS, Eastern Cooperative Oncology Group performance status; CrCl, creatinine clearance; IV, intravenous; PO, oral; SC, subcutaneous; G-CSF, granulocyte colony-stimulating factor; Q4W, every 4 weeks; Q8W, every 8 weeks; NGS, next-generation sequencing; ORR, overall response rate; VGPR, very good partial response; CR, complete response; PFS, progression-free survival; OS, overall survival. aLenalidomide dose adjustments were made for patients with CrCl ≤50 mL/min. bCyclophosphamide-based mobilization was permitted if unsuccessful. cConsolidation was initiated 60-100 days post-transplant. dPatients who complete maintenance Cycles 7-32 may continue single-agent lenalidomide thereafter. eProtocol Amendment 2 allowed for the option to dose daratumumab Q4W based on pharmacokinetic results from study SMM2001 (ClinicalTrials.gov Identifier: NCT02316106). In GRIFFIN, among the D-RVd group who received DR maintenance, 9 patients received DARA Q8W dosing, 57 received DARA Q4W dosing, and 23 switched from DARA Q8W to Q4W dosing.

GRIFFIN: MRD-negativity Rates Improved Throughout the DR Maintenance Period





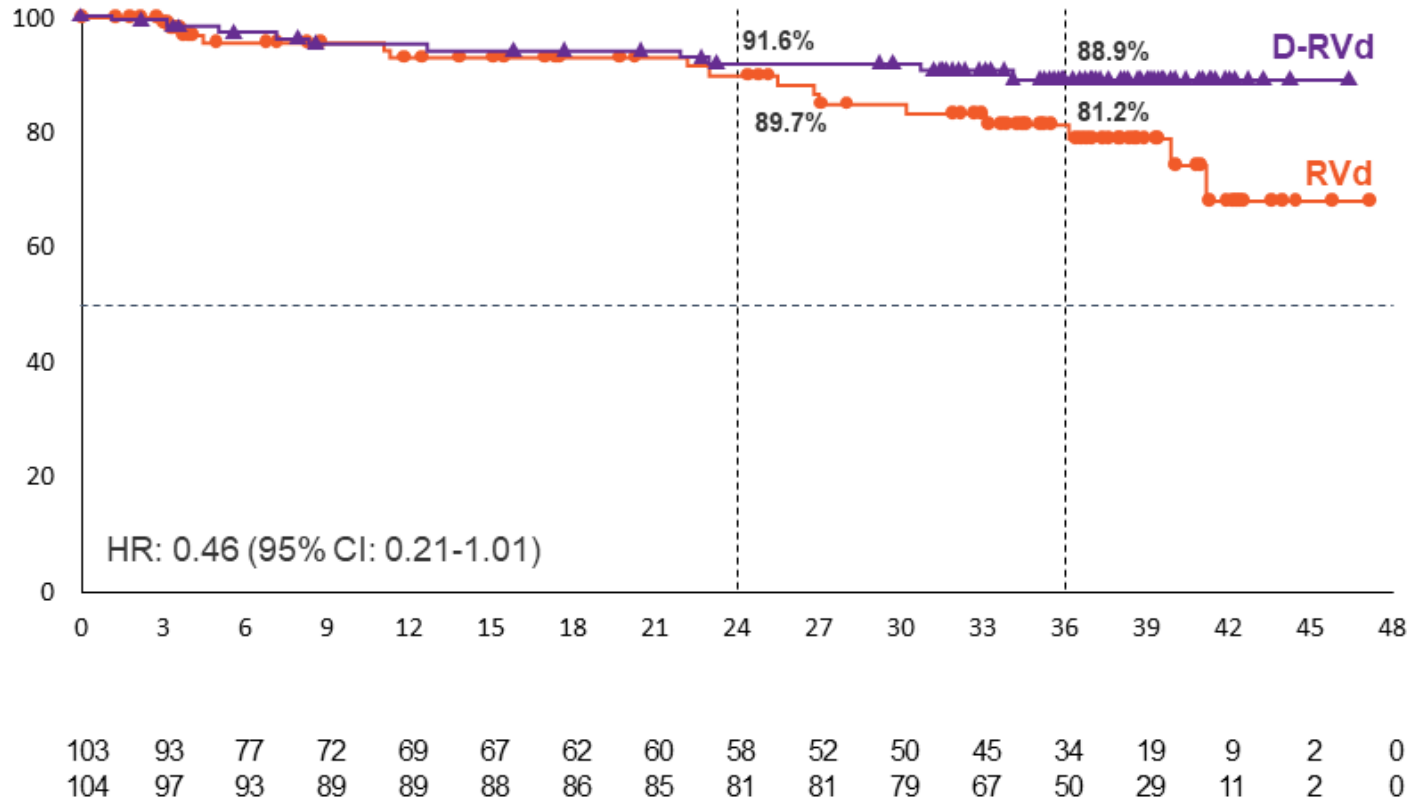
MRD-negative (10^{-5}) conversion rate

- 29% (15/52) of D-RVd patients and 12% (10/82) of RVd patients who were MRD positive at the end of consolidation became MRD negative after 2 years of DR or R maintenance

[a]The threshold of MRD negativity was defined as 1 tumor cell per 10^5 white cells. MRD status is based on the assessment of bone marrow aspirates by NGS in accordance with International Myeloma Working Group criteria. Bone marrow aspirates were assessed at baseline, at first evidence of suspected CR or sCR (including patients with VGPR or better and suspected DARA interference), at the end of induction and consolidation, and after 1 and 2 years of maintenance, regardless of response. Median follow-up was 38.6 months, and MRD-negativity rates are among the ITT population (D-RVd, n = 104; RVd, n = 103).

GRIFFIN: PFS in the ITT Population

- Median follow-up: 38.6 months
- Median PFS was not reached in either group
- There is a positive trend toward improved PFS for D-RVd/DR versus RVd/R
- The separation of the PFS curves begins beyond 1 year of maintenance and suggests a benefit of prolonged DR therapy



HR, hazard ratio.

8

Addition of Isatuximab to Lenalidomide, Bortezomib and Dexamethasone As Induction Therapy for Newly-Diagnosed, Transplant-Eligible Multiple Myeloma Patients: The Phase III GMMG-HD7 Trial

463

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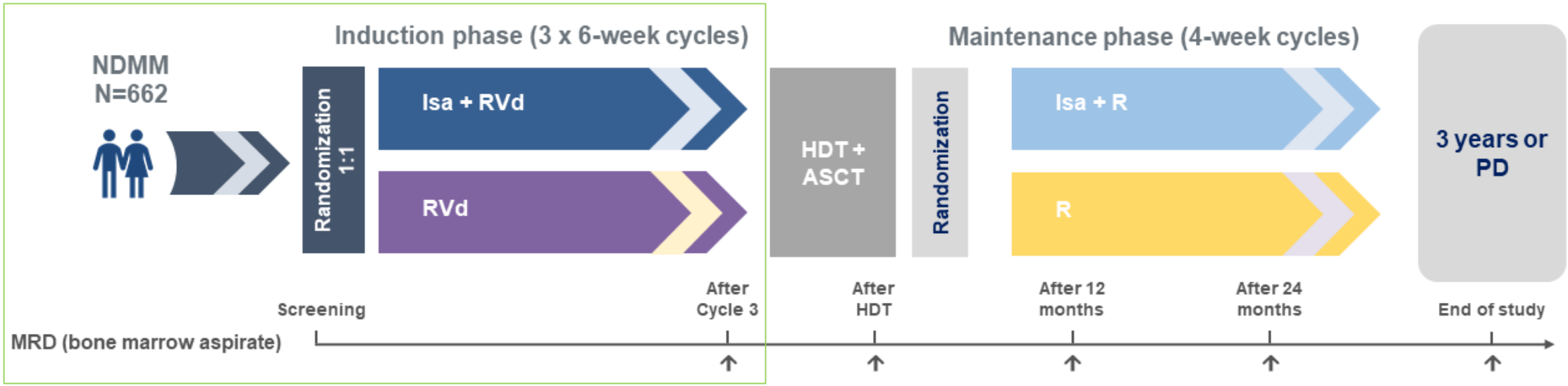
Primary endpoint: MRD negativity at the end of induction phase



Primary endpoint:
- MRD negativity at the end of induction treatment (NGF, sensitivity 10^{-5}) stratified according to R-ISS

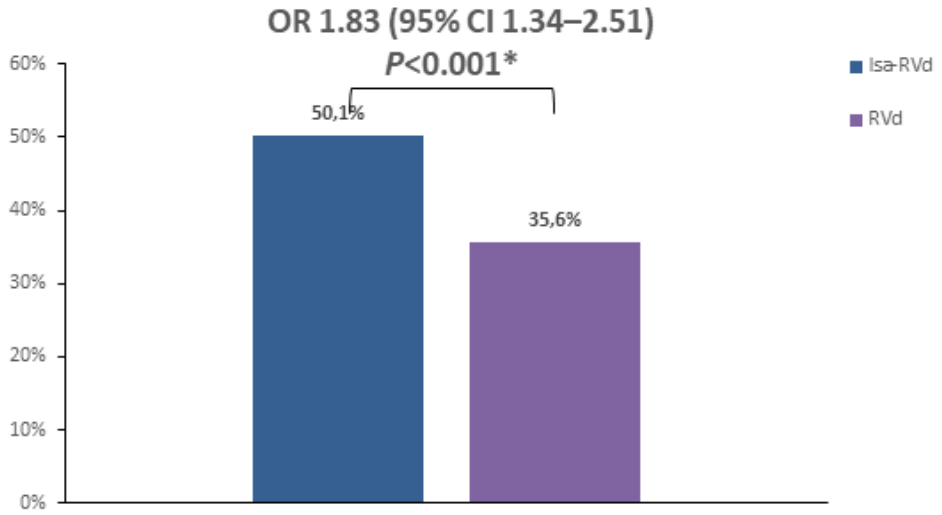
Secondary endpoints:
- CR after induction
- Safety

Data cut-off:
- April 2021

ASCT, autologous stem cell transplant; CR, complete response; d, dexamethasone; HDT, high-dose therapy; Isa, isatuximab; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; NGF, next-generation flow; PD, progressive disease; R, lenalidomide; R-ISS, Revised International Staging System; Te, transplant eligible; V, bortezomib
1. ClinicalTrials.gov: NCT03617731

First primary endpoint, end of induction MRD negativity by NGF (10^{-5}), was met in ITT analysis

Patients with MRD negativity at the end of induction therapy

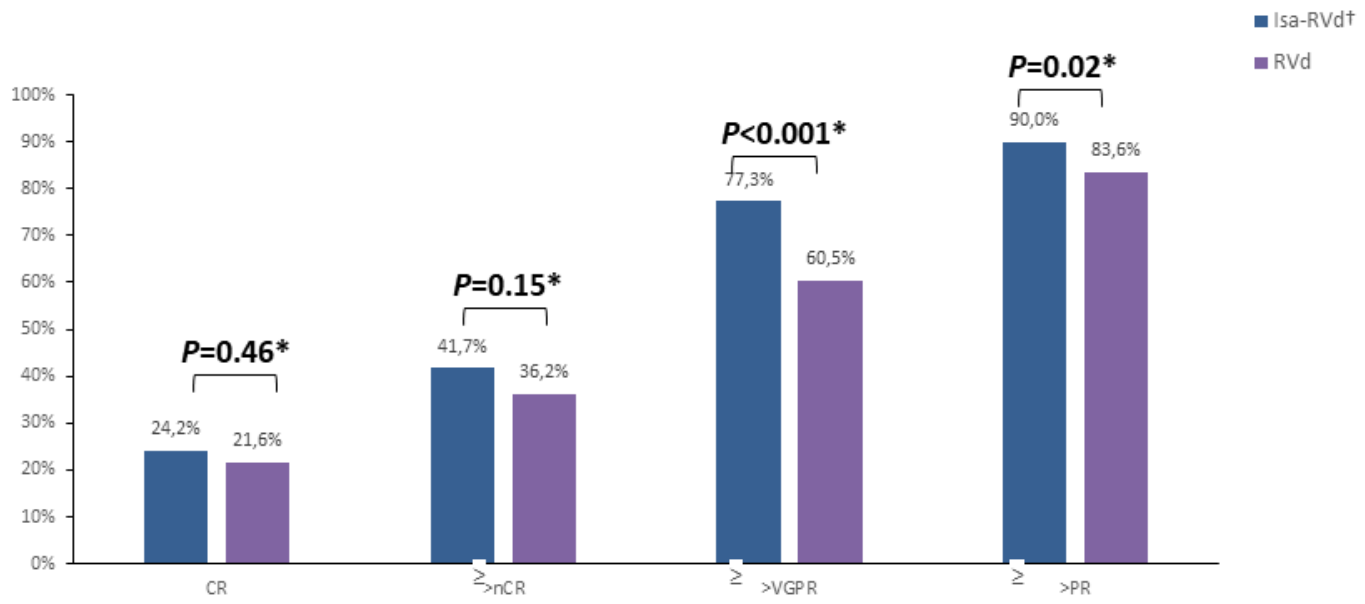


Low number of not assessable/missing† MRD status: Isa-RVd (10.6%) and RVd (15.2%)

Addition of Isa to RVd induction improved rates of MRD negativity* and should be considered a new standard of care in Te NDMM patients

**P* value derived from stratified conditional logistic regression analysis
†Missing NGF-MRD values were due to either patients' loss to follow-up during induction therapy or to missing bone marrow samples or technical failures in measurement counted as non-responders, i.e. NGF-MRD positive
CI, confidence interval; d, dexamethasone; Isa, isatuximab; ITT, intent-to-treat; MRD, minimal residual disease; NGF, next-generation flow; OR, odds ratio; R, lenalidomide; V, bortezomib

Response rates after induction therapy



Although the rates of CR after induction therapy did not differ between the Isa-RVd and RVd arms, there was a significant increase in ≥VGPR rates and ORR with Isa-RVd

*P values derived from Fisher's exact test
†Data adjusted per M-protein interference
CR, complete response; d, dexamethasone; Isa, isatuximab; nCR; near-complete response; ORR, overall response rate; PR, partial response; R, lenalidomide; V, bortezomib; VGPR, very good partial response

Addition of Isa to RVd had limited impact on safety profile

AEs CTCAE grade ≥3, n (%)	Isa-RVd (n=330)	RVd (n=328)
Any AE	210 (63.6)	201 (61.3)
Any serious AE (any grade)	115 (34.8)	119 (36.3)
Deaths	4 (1.2)	8 (2.4)
Investigations* (SOC)	79 (23.9)	77 (23.5)
Blood and lymphatic system disorders (SOC)	85 (25.8)	55 (16.8)
Infections and infestations (SOC)	43 (13.0)	34 (10.4)
Nervous system disorders (SOC)	28 (8.5)	33 (10.1)
Gastrointestinal disorders (SOC)	27 (8.2)	31 (9.5)
Metabolism and nutrition disorders (SOC)	12 (3.6)	26 (7.9)

AEs CTCAE grade ≥3, n (%)	Isa-RVd (n=330)	RVd (n=328)
Specific hematologic AE (PT)		
Leukocytopenia/Neutropenia†	87 (26.4)	30 (9.1)
Lymphopenia	48 (14.5)	65 (19.8)
Anemia	13 (3.9)	20 (6.1)
Thrombocytopenia	21 (6.4)	15 (4.6)
Specific non-hematologic AE (PT)		
Peripheral neuropathy	25 (7.6)	22 (6.7)
Thromboembolic events	5 (1.5)	9 (2.7)
Infusion-related reactions‡	4 (1.2)	NA

A comparable number of patients discontinued induction therapy due to AEs in the Isa-RVd arm vs. RVd arm

*SOC considered as "Investigations" as defined by the CTCAE
†Includes five episodes of febrile neutropenia during induction: Isa-VRd (n=3) vs. VRd (n=2)
‡Infusion-related reactions of CTCAE grade 2 or higher in the Isa-RVd arm were n=42 (12.7%)
AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; d, dexamethasone; Isa, isatuximab; NA, not applicable; PT, preferred term; R, lenalidomide; SOC, system organ class; V, bortezomib

Kapitel 2

Rolle der bispezifischen Antikörper in der Rezidivtherapie: Ausblick auf einen zukünftigen Standard?

Updated Results from MajesTEC-1: Phase 1/2 Study of Teclistamab, a B-Cell Maturation Antigen x CD3 Bispecific Antibody, in Relapsed/Refractory Multiple Myeloma

896

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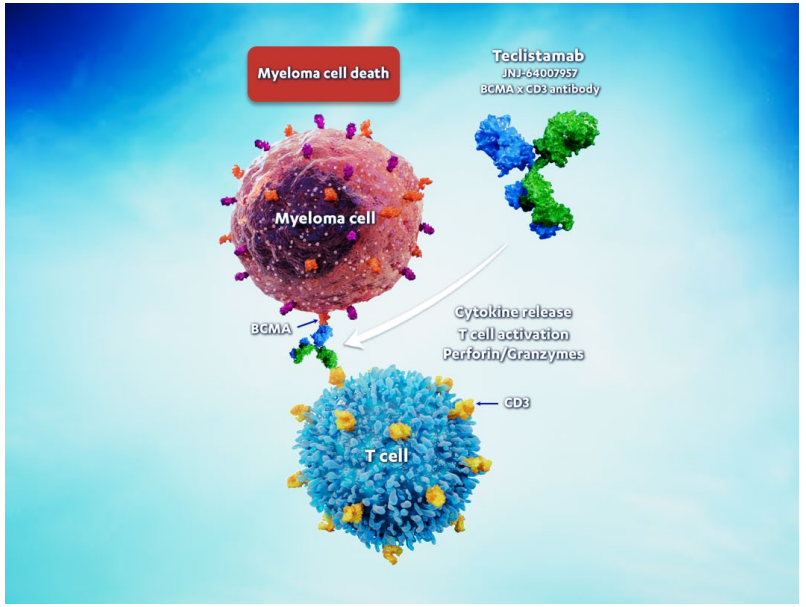
Ergebnisse zum neuen, bispezifischen Anti-BCMA Ak Teclistamab

Majes-TEC-1 Studie

- Teclistamab (JNJ-64007957) is an off-the-shelf, T-cell redirecting, bispecific antibody that binds to CD3 on T cells and BCMA on plasma cells to mediate T-cell activation and subsequent lysis of BCMA-expressing MM cells
- The phase 1 portion of the MajesTEC-1 study identified the RP2D for teclistamab monotherapy: 1.5 mg/kg subcutaneous (SC) QW with step-up doses of 0.06 and 0.3 mg/kg[3]



SCREENING

Cohort A (triple-class exposed)

Key eligibility criteria

- Measurable MM
- RRMM, ≥3PL
- Prior PI, IMiD, and anti-CD38
- No prior BCMA therapy

→

TREATMENT

Week 1

- Step-up doses of teclistamab SC (0.06 and 0.3 mg/kg)

Cycles 1+

- Weekly treatment dose of teclistamab SC 1.5 mg/kg
- Continue until progressive disease

→

POSTTREATMENT

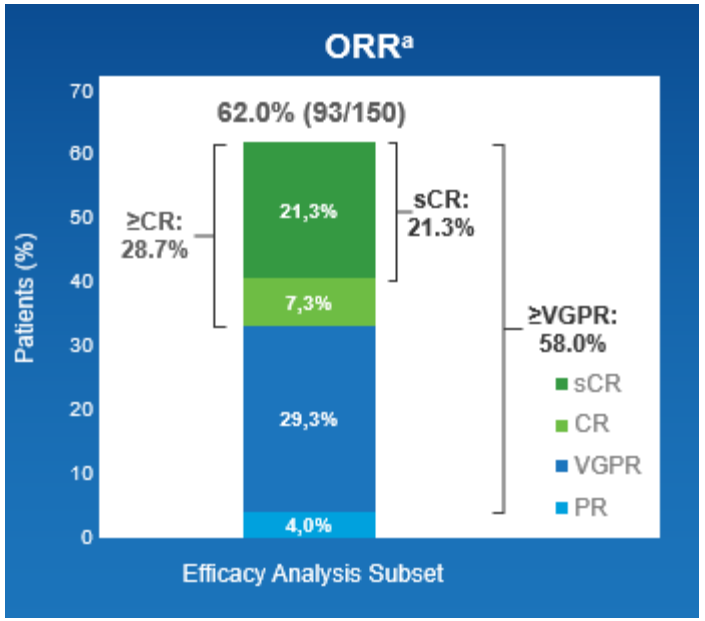
Follow-up

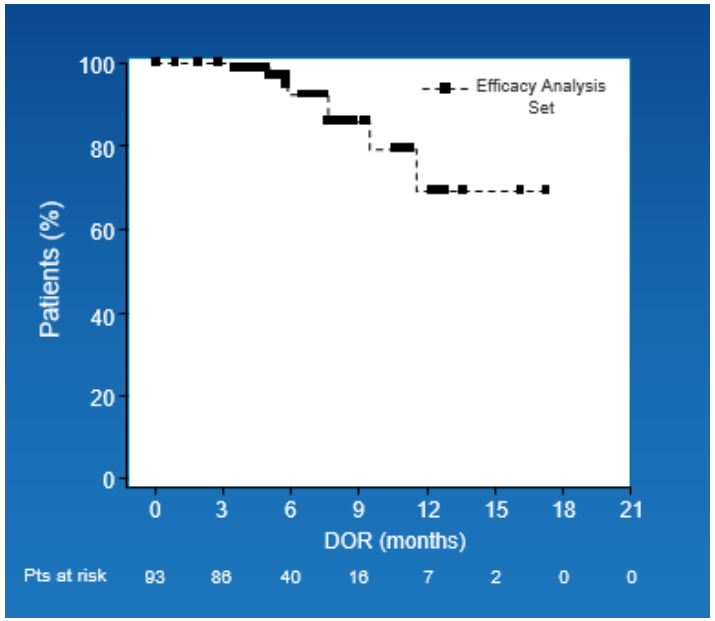
2 years after LPI

Ergebnisse zum neuen, bispezifischen Anti-BCMA Ak Teclistamab

Majes-TEC-1 Studie

Characteristic	Safety Analysis N=165
Age (years), median (range)	64.0 (33–84)
Age ≥75 years, n (%)	24 (14.5)
Prior lines of therapy, median (range)	5.0 (2–14)
Exposure status, n (%)	
Triple-class exposed[f]	165 (100)
Penta-drug exposed[g]	116 (70.3)
Selinexor	6 (3.6)
Refractory status, n (%)	
Triple-class refractory[f]	128 (77.6)
Penta-drug refractory[g]	50 (30.3)
Refractory to last line of therapy	148 (89.7)





Median DOR not reached

Event-free rate for responders

6 month: 92.5% (95% CI: 80.6–97.2)

9 month: 85.9% (95% CI: 70.0–93.7)

PFS rates

6 month: 64.4% (95% CI: 56.0–71.7)

9 month: 58.5% (95% CI: 48.8–67.0)

Ergebnisse zum neuen, bispezifischen Anti-BCMA Ak Teclistamab

Majes-TEC-1 Studie

Safety Analysis Set N=165		
AEs ≥20%, n (%)	Any Grade	Grade 3/4
Neutropenia	108 (65.5)	94 (57.0)
Anemia	82 (49.7)	57 (34.5)
Thrombocytopenia	63 (38.2)	35 (21.2)
Lymphopenia	56 (33.9)	53 (32.1)
CRS	118 (71.5)	1 (0.6)
Injection site erythema	42 (25.5)	0 (0)
Fatigue	41 (24.8)	3 (1.8)
Nausea	40 (24.2)	1 (0.6)
Headache	36 (21.8)	1 (0.6)
Diarrhea	34 (20.6)	4 (2.4)

- **62% ORR with responses that were durable and deepened over time in this heavily pre-treated population**
- **Teclistamab was well tolerated; no patients required dose reduction**
  - The most common AEs were CRS and hematologic events; CRS events were low grade
  - ICANS events were rare, were all grade 1/2,
  - **These data support teclistamab as a promising new, off-the-shelf, T-cell redirecting therapy targeting BCMA for patients with RRMM**

Kapitel 3

Nach Zulassung der CAR-T Zellbehandlung für das rezidivierte Multiple Myelom: Was sind die neuen Ergebnisse?

Updated Results from CARTITUDE-1: Phase 1b/2Study of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen–Directed Chimeric Antigen Receptor T Cell Therapy, in Patients With Relapsed/Refractory Multiple Myeloma

549

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Cilta-Cel in der Therapie des RRMM

Update nach 2 Jahren Nachbeobachtung

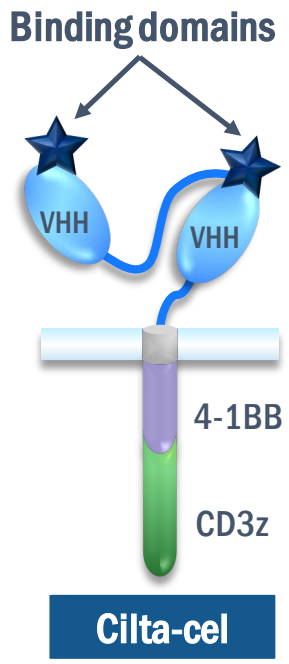
Ciltacabtagene autoleucel (cilta-cel; JNJ-68284528) is a chimeric antigen receptor T-cell therapy for the treatment of patients with RRMM

In the phase 1b/2 CARTITUDE-1 study, early, deep, and durable responses were observed with a single cilta-cel infusion in heavily pretreated patients with RRMM

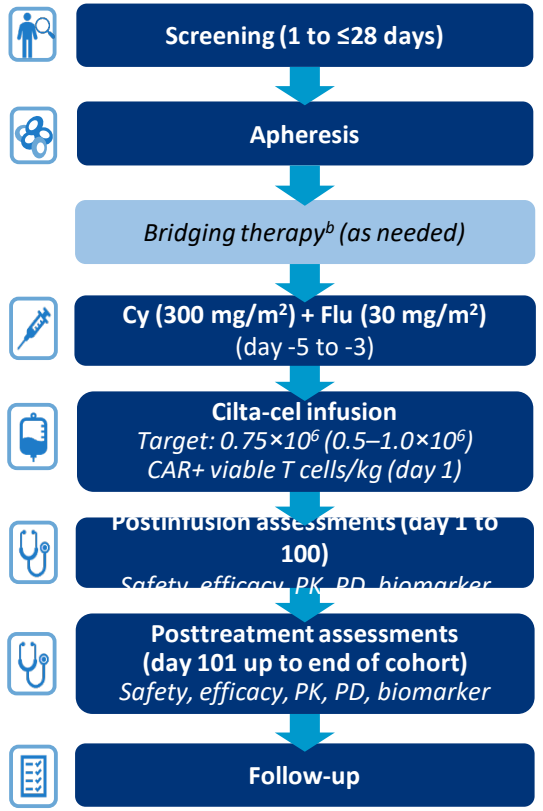
Here, updated results are reported from the CARTITUDE-1 study with a longer duration of follow-up (median ~2 years)

Key eligibility criteria

- Progressive MM per IMWG criteria
- ECOG PS ≤1
- Measurable disease
- ≥3 prior therapies or double refractory
- Prior PI, IMiD, anti-CD38 antibody exposure



2 BCMA-targeting single-domain antibodies designed to confer avidity

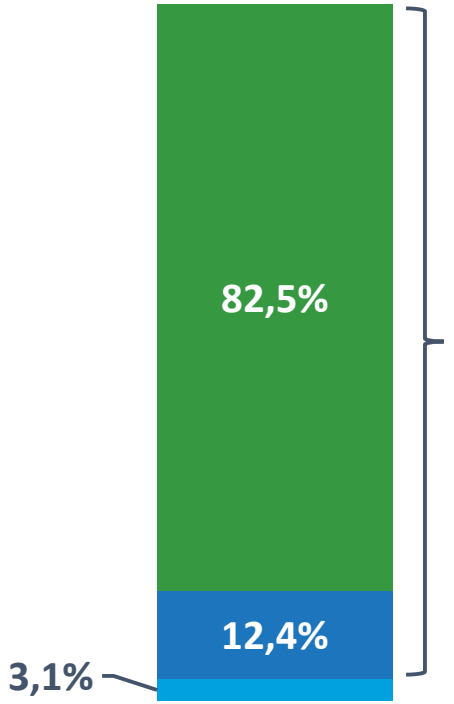


Cilta-Cel in der Therapie des RRMM

Update nach 2 Jahren Nachbeobachtung

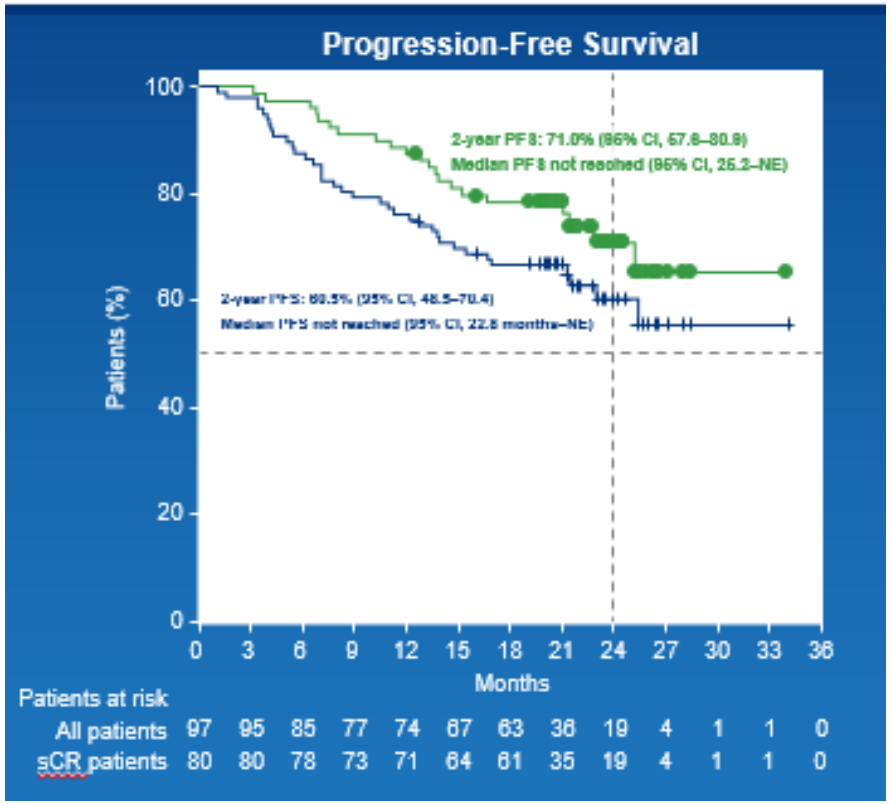
Characteristics	N=97
Prior lines of therapy, median (range)	6.0 (3–18)
Prior lines of therapy, n (%)	
≥5	64 (66.0)
Triple-class exposed,[b] n (%)	97 (100)
Penta-drug exposed,[c] n (%)	81 (83.5)
Triple-class refractory[b]	85 (87.6)
Penta-drug refractory[c]	41 (42.3)
Refractory status, n (%)	
Carfilzomib	63 (64.9)
Pomalidomide	81 (83.5)
Anti-CD38 antibody	96 (99.0)
Refractory to last line of therapy, n (%)	96 (99.0)
Years since diagnosis, median (range)	5.9 (1.6–18.2)

ORR: 97.9% (95/97)



≥VGPR: 94.9%

Best response = sCR VGPR PR



- 2-year PFS and OS rates were 60.5% and 74.0%, respectively
- MRD negativity (at 10^{-5}) was achieved in 92% of evaluable patients

Zusammenfassung | Take-Home-Messages

- In der Erstlinientherapie der transplantierbaren Patienten ist die Quadruplet-Therapie unbedingt in der Induktionsbehandlung anzustreben und etabliert sich weiter als Standard mit den besten Remissions- und PFS Daten, die bisher erreicht wurden
- In Deutschland zugelassen: D-VTd für Induktion und Konsolidierung
- In der Rezidivtherapie liegen nun deutlich konsolidiertere Daten für die CAR-T Zelltherapie und die bispezifischen Antikörper vor
- Bispezifische Antikörper sind off-the-shelf verfügbar, zeigen hohes Ansprechen, das Nebenwirkungsprofil ist günstig
- CAR-T Zelltherapie, insbesondere mit Cilta-Cel, zeigen die bislang besten Ansprechraten, die je in Rezidivtherapien erreicht wurden und setzen sich auch zunehmend in günstige Ansprechdauern und PFS Daten um

Die Kurzpräsentationen sind online unter

www.lymphome.de/ash2021

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